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Samson

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[54] **HIGH PERFORMANCE SUPERELASTIC
ALLOY BRAID REINFORCED CATHETER**

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[73] Assignee: **Target Therapeutics, Inc.**, Fremont,
Calif.

[*] Notice: The term of this patent shall not extend
beyond the expiration date of Pat. No.
5,702,373.

[21] Appl. No.: **484,943**

[22] Filed: **Jun. 7, 1995**

Related U.S. Application Data

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[51] **Int. Cl.⁶** **A61M 25/00**

[52] **U.S. Cl.** **604/282; 604/280**

[58] **Field of Search** 604/280-282,
604/264; 128/656-658; 138/123-127, 137,
138, 140, 145

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3,416,531	12/1968	Edwards .
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3,757,768	9/1973	Kline .
3,924,632	12/1975	Cook .
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4,676,229	6/1987	Krasnicki et al. .
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Primary Examiner—Ronald Stright, Jr.

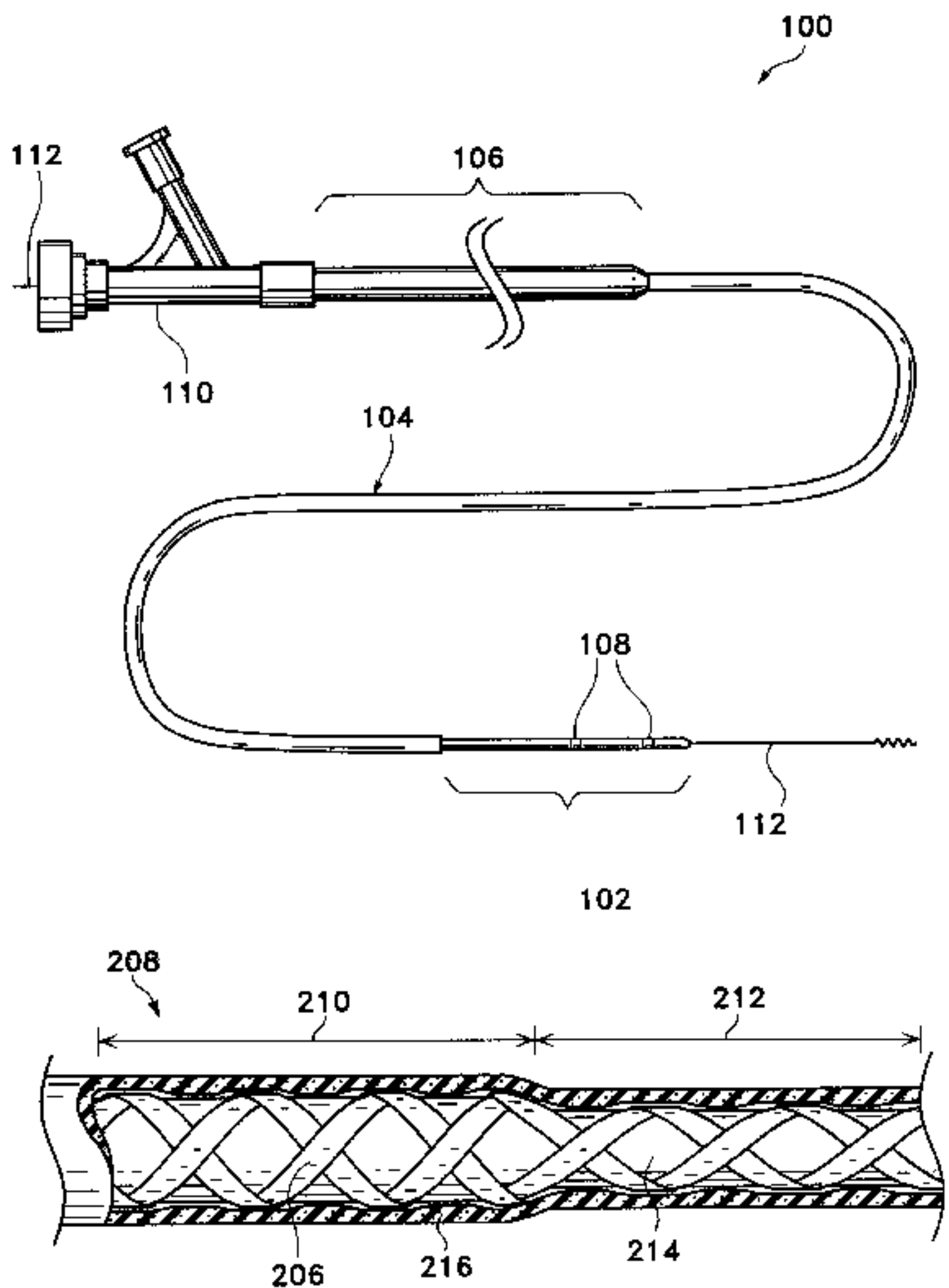
Assistant Examiner—A. T. Nguyen

Attorney, Agent, or Firm—Morrison & Foerster, LLP

[57] **ABSTRACT**

This is a section of a catheter used in making a catheter assembly suitable for accessing a tissue target within the body, typically a target which is accessible through the vascular system. The catheter section uses a braided metallic reinforcing member, typically of superelastic alloy ribbon, situated within the catheter body in such a way to create a catheter having an exceptionally thin wall, controlled stiffness, high resistance to kinking, and complete recovery in vivo from kinking situations. The braid may have a single pitch or may vary in pitch along the axis of the catheter or catheter section. The braided ribbon reinforcing member typically is placed between a flexible outer tubing member and an inner tubing member to produce a catheter section which is very flexible but highly kink. resistant. The catheter sections may be used alone or in conjunction with other catheter sections either made using the concepts shown herein or made in other ways.

47 Claims, 6 Drawing Sheets



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			5,279,596	1/1994	Castaneda et al. 604/282
			5,313,967	5/1994	Lieber et al. .
			5,336,205	8/1994	Zenzen et al. .
5,057,092	10/1991	Webster, Jr. .	5,356,388	10/1994	Sepetka et al. 604/164
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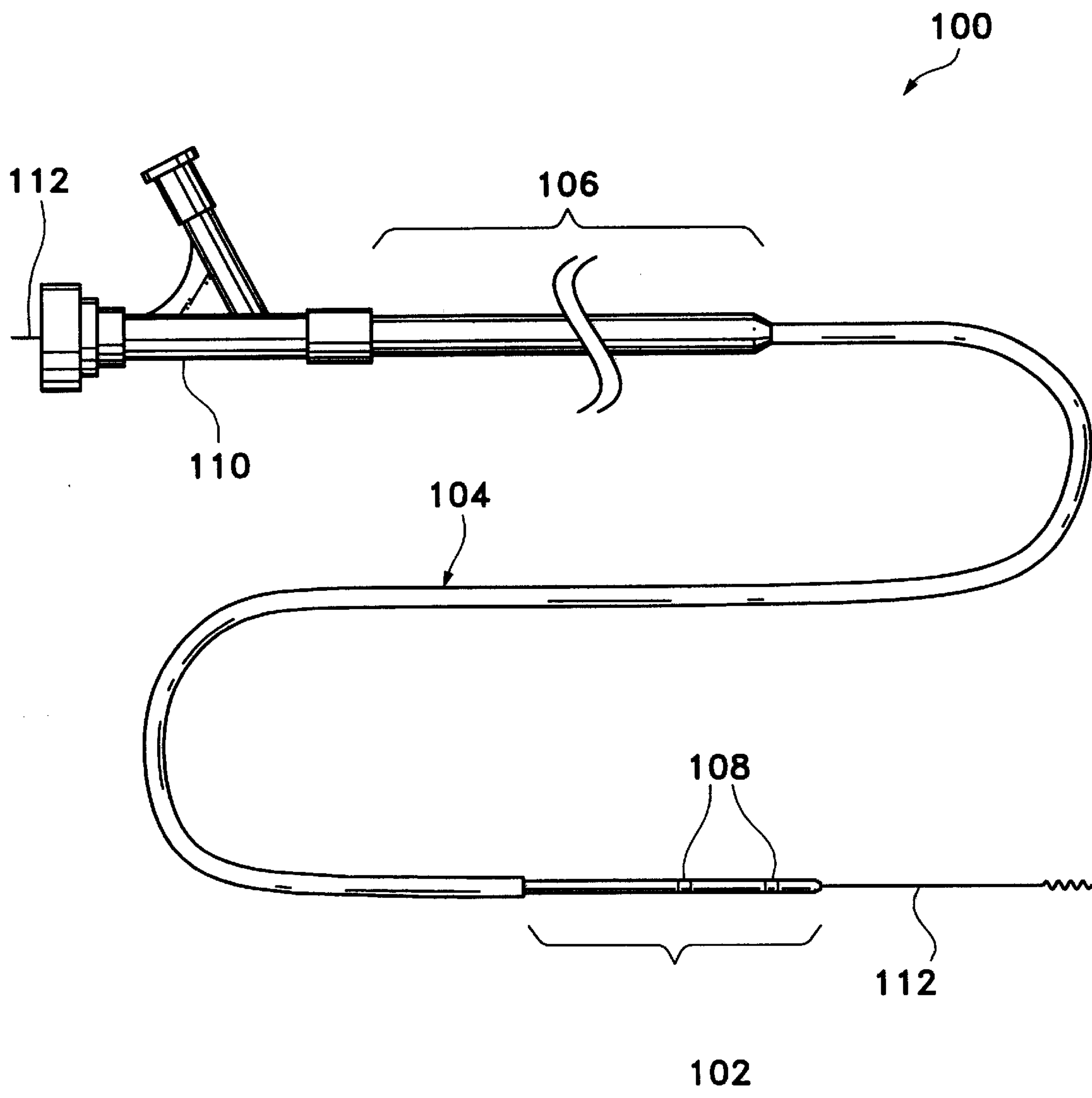


Fig. 1

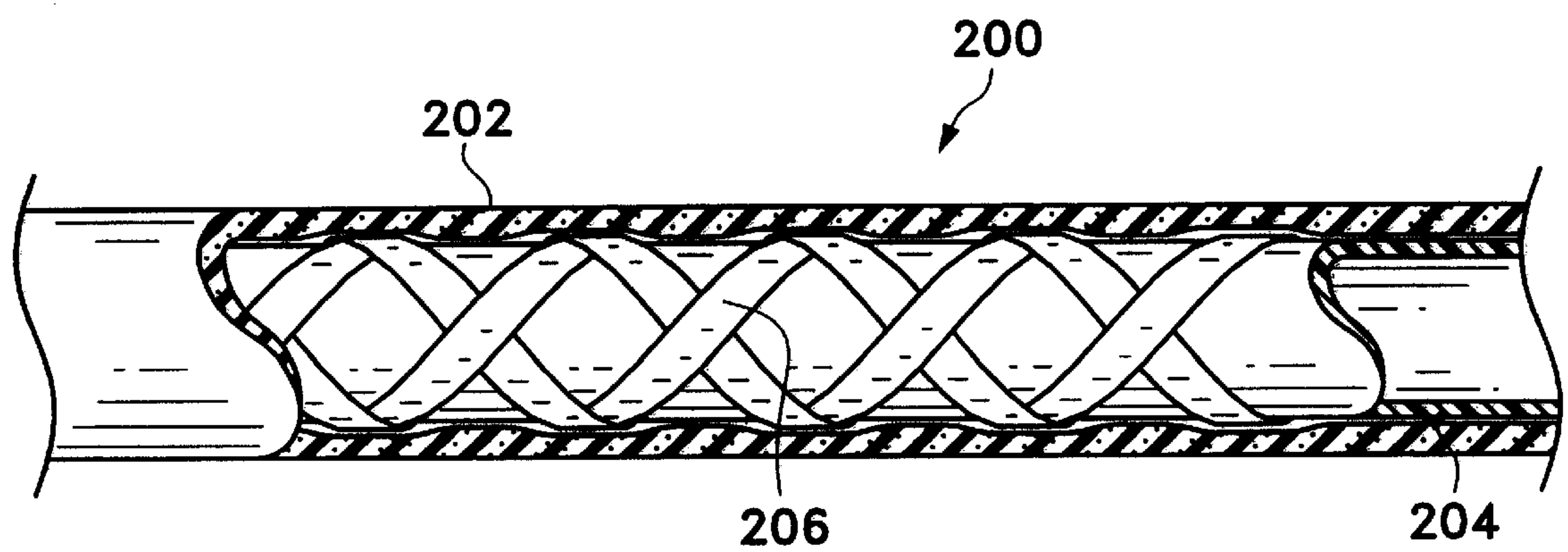


Fig. 2

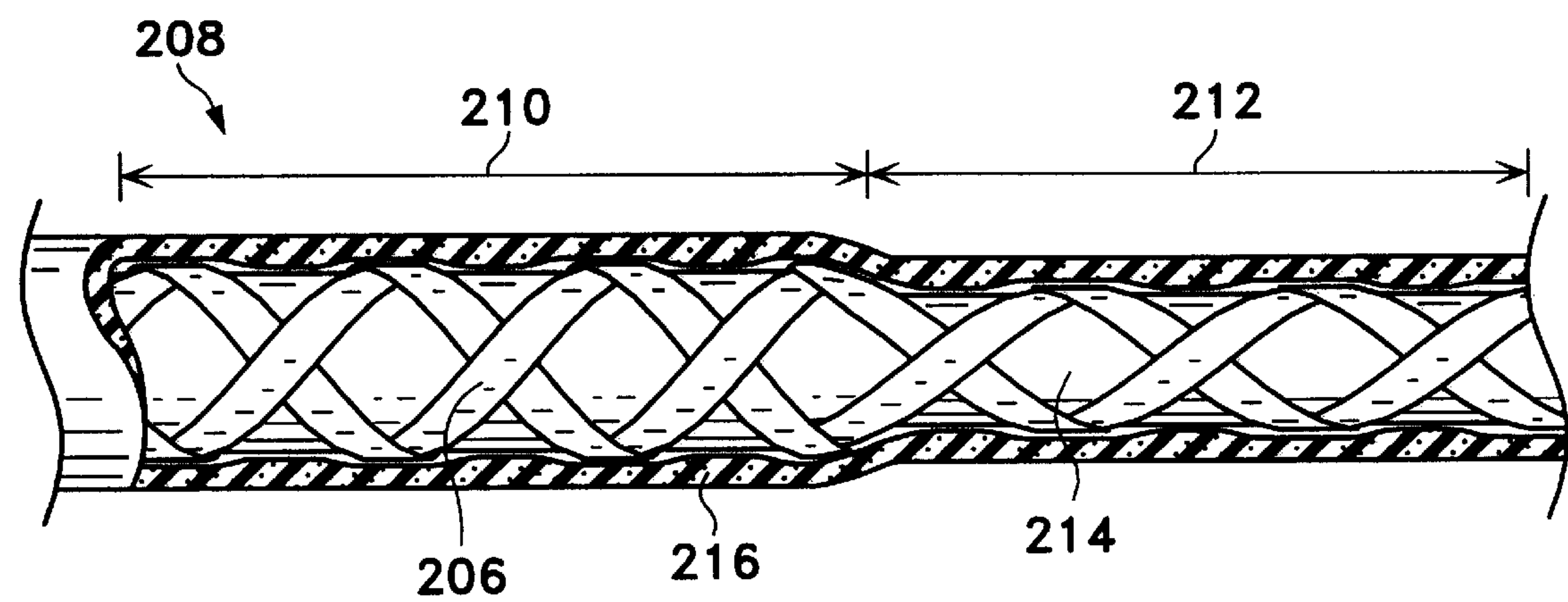


Fig. 3

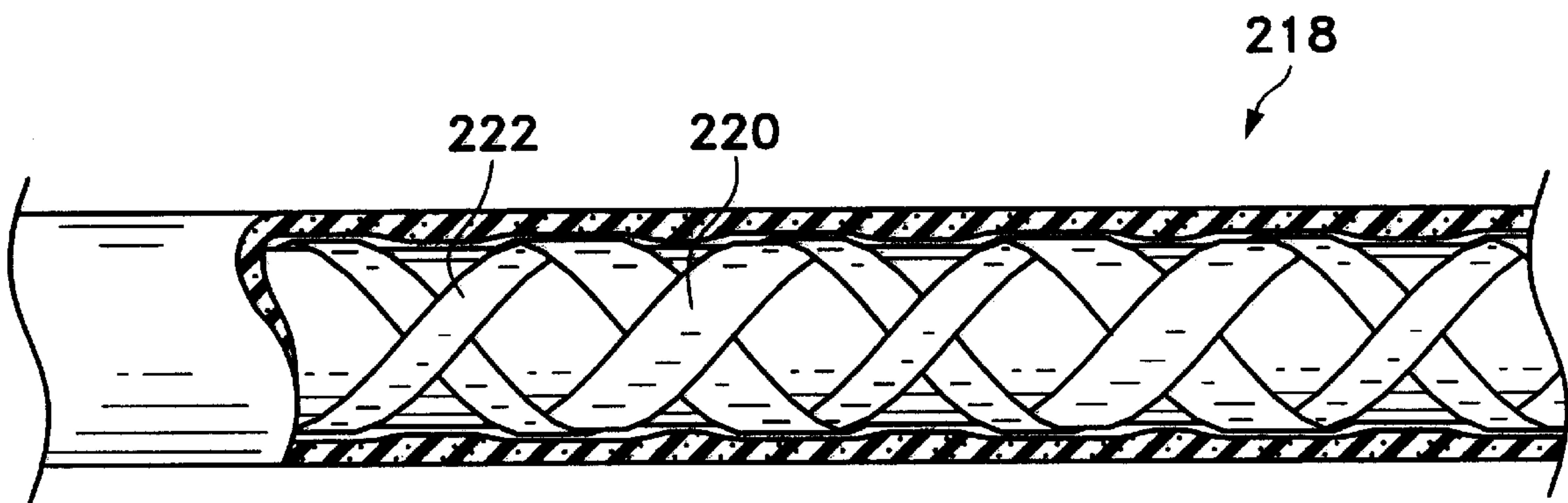


Fig. 4

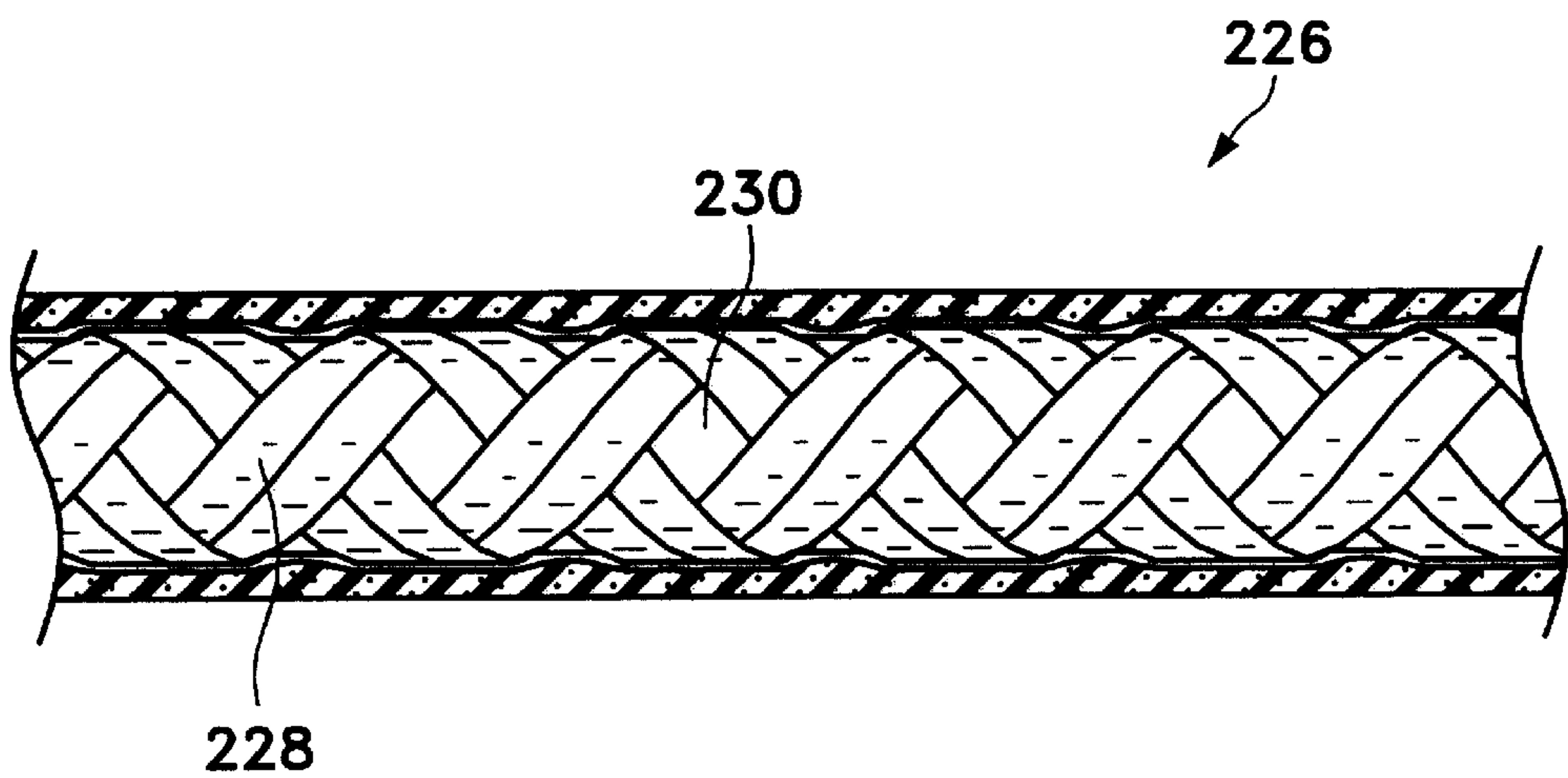


Fig. 5

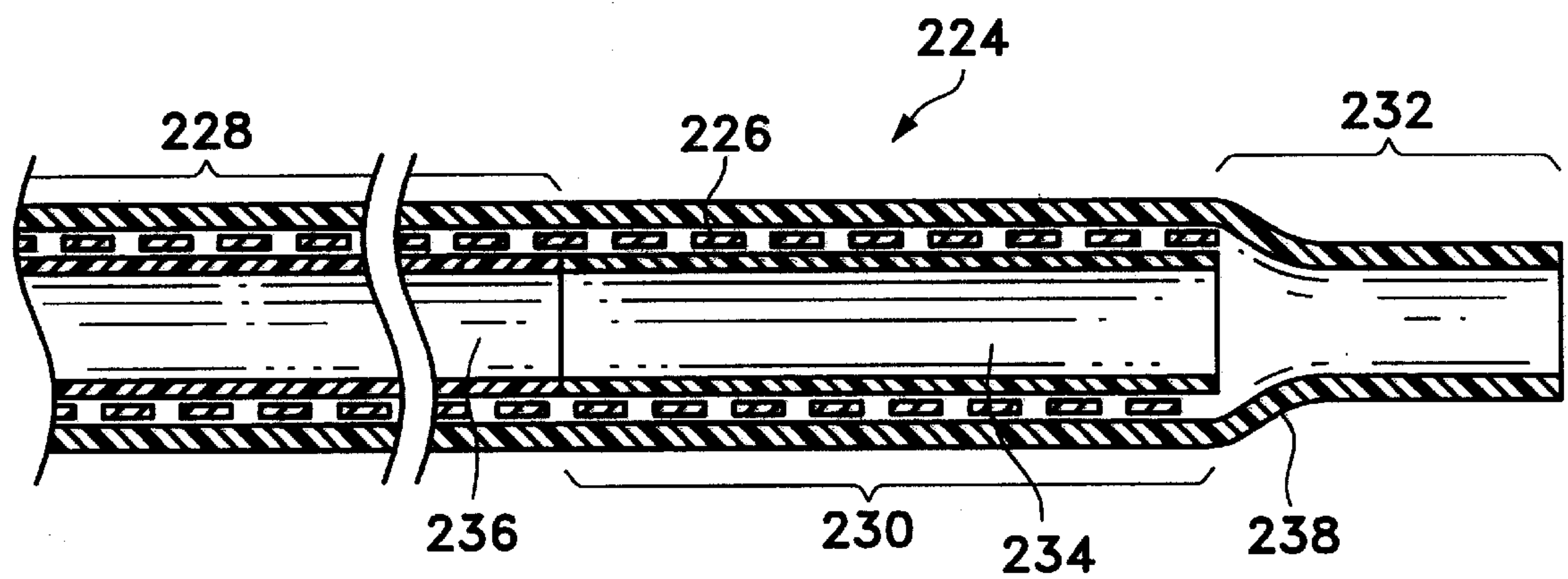


Fig. 6

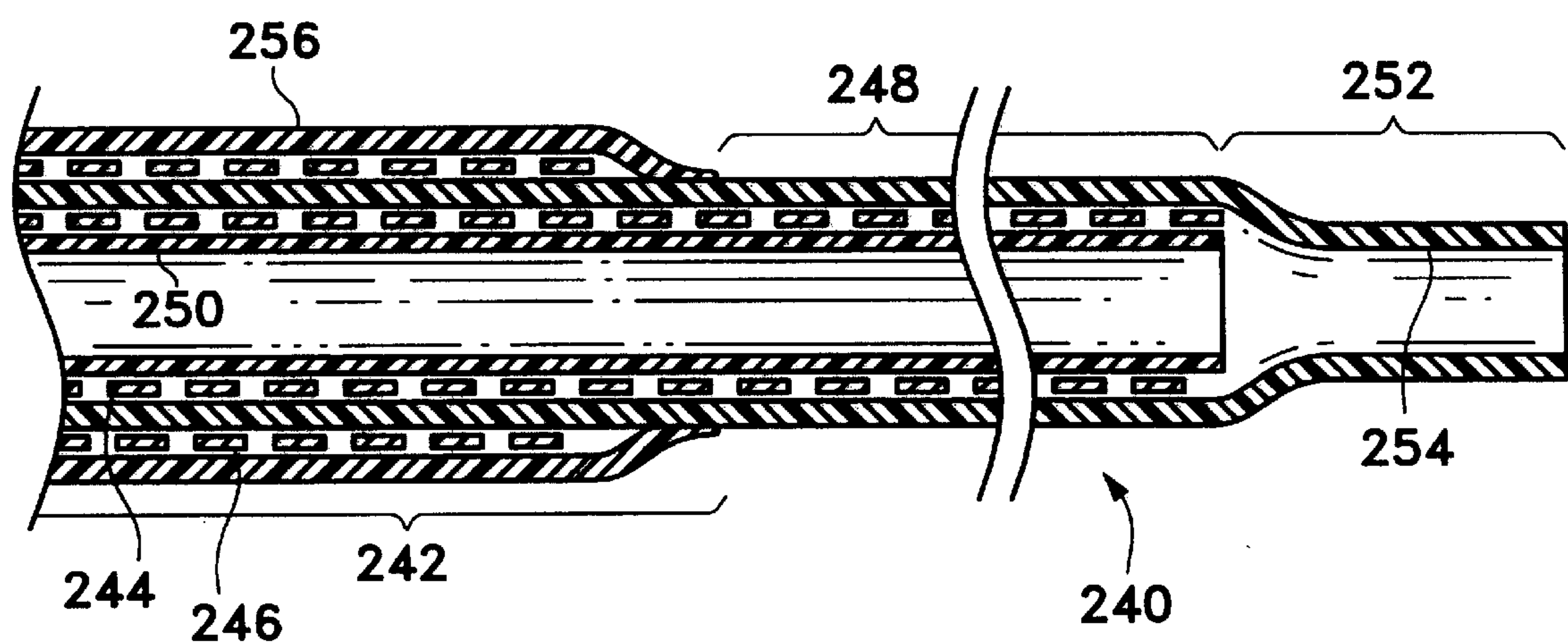


Fig. 7

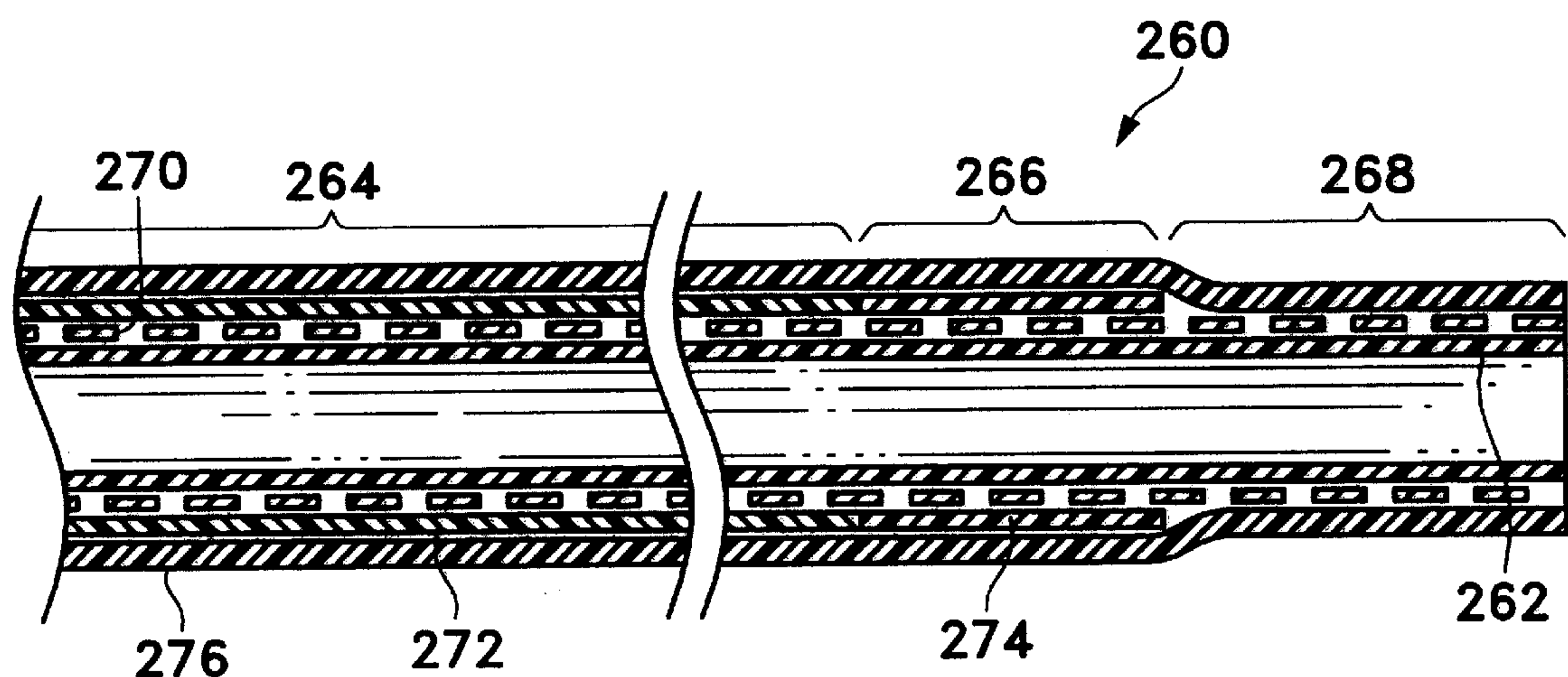


Fig. 8

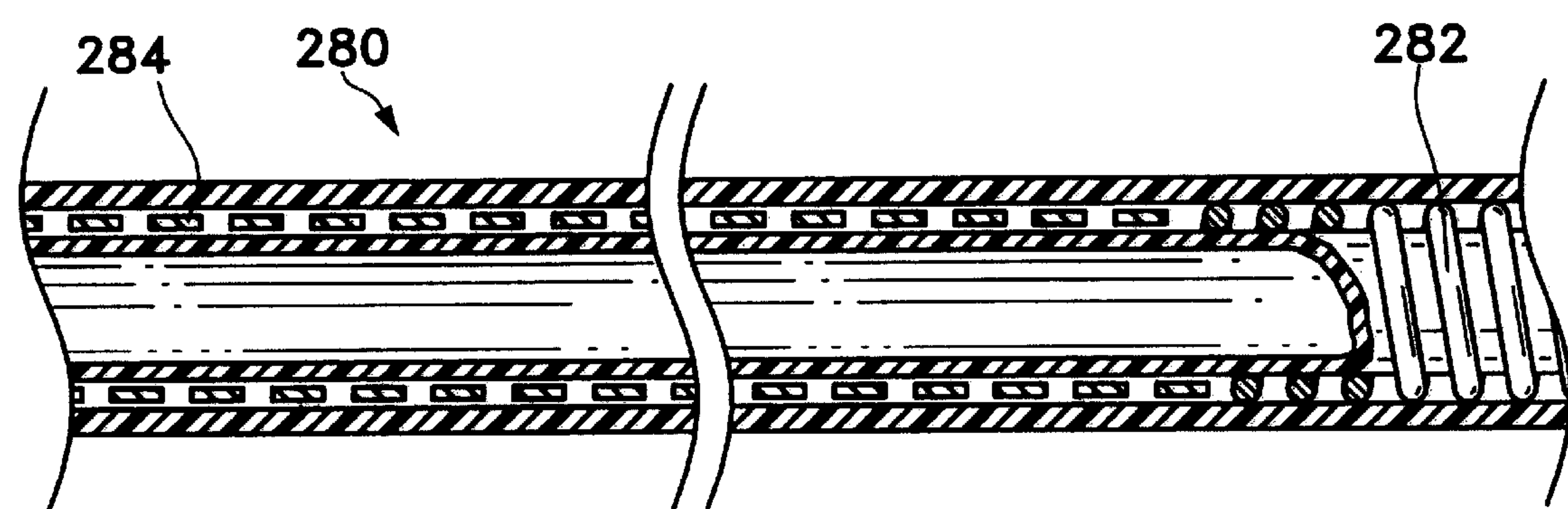


Fig. 9

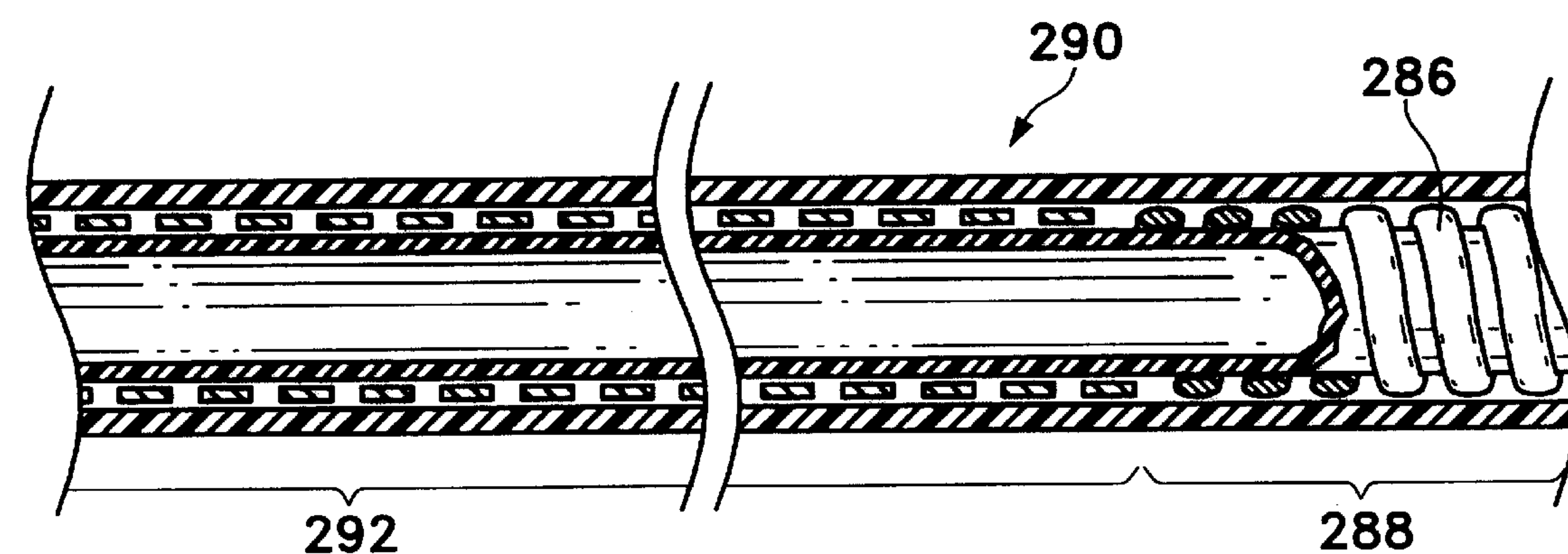


Fig. 10

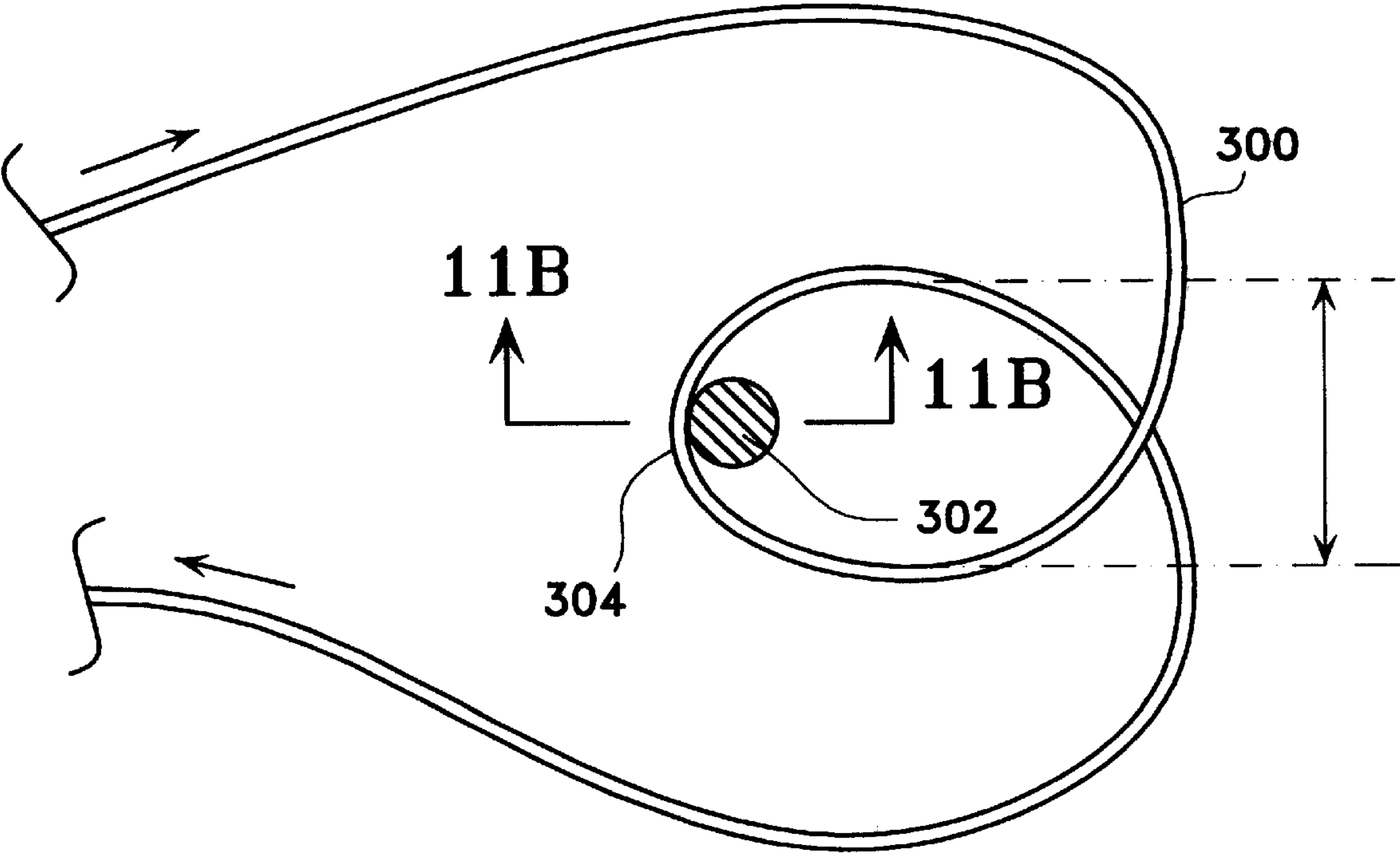


Fig. 11A

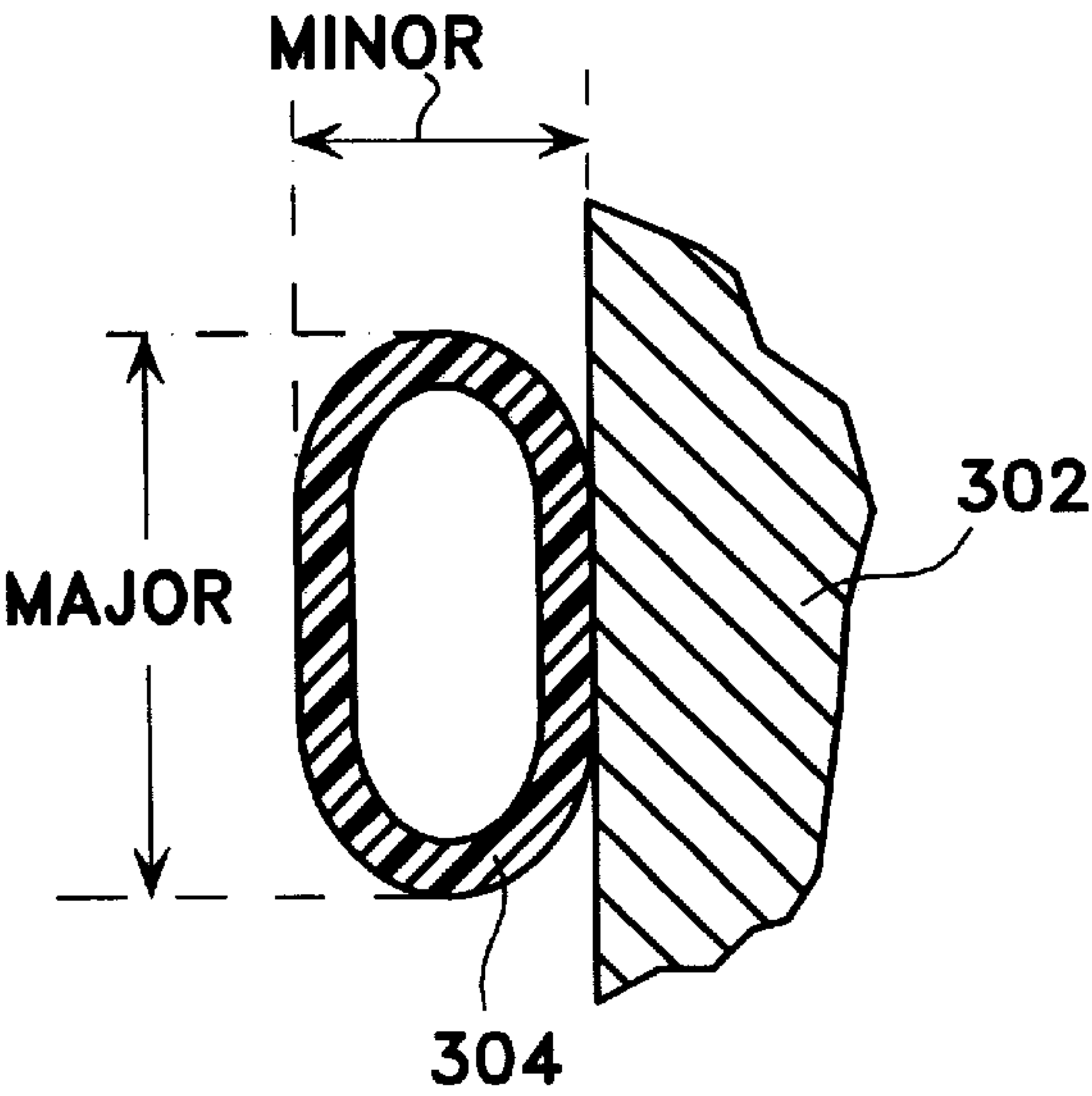


Fig. 11B

HIGH PERFORMANCE SUPERELASTIC ALLOY BRAID REINFORCED CATHETER

This application is a division of application Ser. No. 08/430,455 filed Apr. 28, 1995, pending.

FIELD OF THE INVENTION

This invention is a surgical device. In particular, it is a section of a catheter used in making a catheter assembly suitable for accessing a tissue target within the body, typically a target which is accessible through the vascular system. Central to the invention is the use of a braided metallic reinforcing member, typically of superelastic alloy ribbon, situated within the catheter body in such a way to create a catheter having an exceptionally thin wall, controlled stiffness, high resistance to kinking, and complete recovery in vivo from kinking situations. The braid may have a single pitch or may vary in pitch along the axis of the catheter or catheter section. The braided ribbon reinforcing member typically is placed between a flexible outer tubing member and an inner tubing member to produce a catheter section which is very flexible but highly kink resistant.

The catheter sections made according to this invention may be used alone or in conjunction with other catheter sections either made using the concepts shown herein or made in other ways.

BACKGROUND OF THE INVENTION

Catheters are increasingly used to access remote regions of the human body and, in doing so, delivering diagnostic or therapeutic agents to those sites. In particular, catheters which use the circulatory system as the pathway to these treatment sites are especially practical. Catheters are also used to access other regions of the body, e.g., genito-urinary regions, for a variety of therapeutic and diagnostic reasons. One such treatment of diseases of the circulatory system is via angioplasty (PCA). Such a procedure uses catheters having balloons on their distal tips. It is similarly common that those catheters are used to deliver a radiopaque agent to the site in question prior to the PCA procedure to view the problem prior to treatment.

Often the target which one desires to access by catheter is within a soft tissue such as the liver or the brain. These are difficult sites to reach. The catheter must be introduced through a large artery such as those found in the groin or in the neck and then be passed through ever-narrower regions of the arterial system until the catheter reaches the selected site. Often such pathways will wind back upon themselves in a multi-looped path. These catheters are difficult to design and to utilize in that they must be fairly stiff at their proximal end so to allow the pushing and manipulation of the catheter as it progresses through the body, and yet must be sufficiently flexible at the distal end to allow passage of the catheter tip through the loops and increasingly smaller blood vessels mentioned above and yet at the same time not cause significant trauma to the blood vessel or to the surrounding tissue. Further details on the problems and an early, but yet effective, way of designing a catheter for such a traversal may be found in U.S. Pat. No. 4,739,768, to Engelson. These catheters are designed to be used with a guidewire. A guidewire is simply a wire, typically of very sophisticated design, which is the "scout" for the catheter. The catheter fits over and slides along the guidewire as it passes through the vasculature. Said another way, the guidewire is used to select the proper path through the vasculature with the urging of the attending physician and the catheter slides along behind once the proper path is established.

There are other ways of causing a catheter to proceed through the human vasculature to a selected site, but a guidewire-aided catheter is considered to be both quite quick and somewhat more accurate than the other procedures. One such alternative procedure is the use of a flow-directed catheter. These devices often have a small balloon situated on the distal end of the catheter which may be alternately deflated and inflated as the need to select a route for the catheter is encountered.

This invention is an adaptable one and may be used in a variety of catheter formats. The invention utilizes the concept of combining one or more polymeric tubes with a metallic braid comprising ribbons of a superelastic alloy. The construction technique has the benefit of producing catheter sections having small overall diameters but with exceptional strength, resistance to kinking, and recovery from kinking (even in vivo) should such kinking occur. This catheter may be used in conjunction with a guidewire, but the catheter body may also be used as a flow-directed catheter with the attachment of a balloon or in combination with a specifically flexible tip, as is seen, for instance, in U.S. Pat. No. 5,336,205 to Zenzen et al., the entirety of which is incorporated by reference.

The use of braids in a catheter body is not a novel concept. Typical background patents are discussed below. However, none of these documents have used our concept to produce a catheter which has the physical capabilities of the catheter of this invention.

Multi-Wrap Catheters

There are a number of catheters discussed in the literature which utilize catheter bodies having multiply-wrapped reinforcing material. These catheters include structures having braided bands or ones in which the spirally wound material is simply wound in one direction and the following layer or layers are wound in the other.

Crippendorf, U.S. Pat. No. 2,437,542, describes a "catheter-type instrument" which is typically used as a ureteral or urethral catheter. The physical design is said to be one having a distal section of greater flexibility and a proximal section of lesser flexibility. The device is made of intertwined threads of silk, cotton, or some synthetic fiber. It is made by impregnating a fabric-based tube with a stiffening medium which renders the tube stiff yet flexible. The thus-plasticized tubing is then dipped in some other medium to allow the formation of a flexible varnish-like layer. This latter material may be a tung oil base or a phenolic resin and a suitable plasticizer. There is no indication that this device is of the flexibility described herein. Additionally, it appears to be the type which is used in some region other than in the body's periphery or in its soft tissues.

Similarly, U.S. Pat. No. 3,416,531, to Edwards, shows a catheter having braiding-edge walls. The device further has additional layers of other polymers such as TEFLON and the like. The strands found in the braiding in the walls appear to be threads having circular cross-sections. There is no suggestion of constructing a device using ribbon materials. Furthermore, the device is shown to be fairly stiff in that it is designed so that it may be bent using a fairly large handle at its proximal end.

U.S. Pat. No. 3,924,632, to Cook, shows a catheter body utilizing fiberglass bands wrapped spirally for the length of the catheter. As is shown in FIG. 2 and the explanation of the figure at column 3, lines 12 and following, the catheter uses fiberglass bands which are braided, that is to say, bands which are spiralled in one direction cross over and under

bands which are spiraled in the opposite direction. Additionally, it should be observed that FIG. 3 depicts a catheter shaft having both an inner lining or core 30 and an outer tube 35.

U.S. Pat. No. 4,425,919, to Alston, Jr. et al., shows a multilayered assembly using multi-stranded flat wire braid. The braid 14 in FIG. 3 further covers an interior tubing or substrate 12.

U.S. Pat. No. 4,484,586 shows a method for the production of a hollow, conductive medical tubing. The conductive wires are placed in the walls of hollow tubing specifically for implantation in the human body, particularly for pacemaker leads. The tubing is preferably made of an annealed copper wire which has been coated with a body-compatible polymer such as a polyurethane or a silicone. After coating, the copper wire is wound into a tube. The wound substrate is then coated with still another polymer to produce a tubing having spiral conducting wires in its wall.

A document showing the use of a helically wound ribbon of flexible material in a catheter is U.S. Pat. No. 4,516,972, to Samson. This device is a guiding catheter and it may be produced from one or more wound ribbons. The preferred ribbon is an aramid material known as Kevlar 49. Again, this device is a device which must be fairly stiff. It is a device which is designed to take a "set" and remain in a particular configuration as another catheter is passed through it. It must be soft enough so as not to cause substantial trauma, but it is certainly not for use with a guidewire. It would not meet the flexibility criteria required of the inventive catheter described herein.

U.S. Pat. No. 4,806,182, to Rydell et al., shows a device using a stainless steel braid imbedded in its wall and having an inner layer of a polyfluorocarbon. The process also described therein is a way to laminate the polyfluorocarbon to a polyurethane inner layer so as to prevent delamination.

U.S. Pat. No. 4,832,681, to Lenck, shows a method and apparatus useful for artificial fertilization. The device itself is a long portion of tubing which, depending upon its specific materials of construction, may be made somewhat stiffer by the addition of a spiral reinforcement comprising stainless steel wire.

U.S. Pat. No. 4,981,478, to Evard et al., discloses a multi-sectioned or composite vascular catheter. The interior section of the catheter appears to have three sections making up the shaft. The most interior (and distal) section, appears to be a pair of coils 13 and 24 having a polymeric tubing member 21 placed within it. The next, more proximal, section is 41, and FIG. 4 shows it to be "wrapped or braided" about the next inner layer discussed just above. The drawing does not show it to be braided but, instead, a series of spirally wrapped individual strands. Finally, the outermost tubular section of this catheter core is another fiber layer 49, of similar construction to the middle section 26 discussed just above. No suggestion is made that any of these multiple layers be simplified into a single, spirally-wrapped layer adhesively bound to an outer polymeric covering.

Another catheter showing the use of braided wire is shown in U.S. Pat. No. 5,037,404, to Gold et al. Mention is made in Gold et al of the concept of varying the pitch angle between wound strands so to result in a device having differing flexibilities at differing portions of the device. The differing flexibilities are caused by the difference in pitch angle. No mention is made of the use of ribbon, nor is any specific mention made of the particular uses to which the Gold et al. device may be placed.

U.S. Pat. No. 5,057,092, to Webster, Jr., shows a catheter device used to monitor cardiovascular electrical activity or to electrically stimulate the heart. The catheter uses braided helical members having a high modulus of elasticity, e.g., stainless steel. The braid is a fairly complicated, multi-component pattern shown very well in FIG. 2.

U.S. Pat. No. 5,176,660 shows the production of catheters having reinforcing strands in their sheath wall. The metallic strands are wound throughout the tubular sheath in a helical crossing pattern so to produce a substantially stronger sheath. The reinforcing filaments are used to increase the longitudinal stiffness of the catheter for good "pushability". The device appears to be quite strong and is wound at a tension of about 250,000 lb./in.² or more. The flat strands themselves are said to have a width of between 0.006 and 0.020 inches and a thickness of 0.0015 and 0.004 inches. There is no suggestion to use these concepts in devices having the flexibility and other configurations described below.

Another variation which utilizes a catheter wall having helically placed liquid crystal fibrils is found in U.S. Pat. No. 5,248,305, to Zdrahala. The catheter body is extruded through an annular die, having relatively rotating inner and outer mandrel dies. In this way, the tube containing the liquid crystal polymer plastic-containing material exhibits a bit of circumferential orientation due to the rotating die parts. At column 2, line 40 and following, the patent suggests that the rotation rate of the inner and outer walls of the die may be varied as the tube is extruded, with the result that various sections of the extruded tube exhibit differing stiffnesses.

U.S. Pat. No. 5,217,482 shows a balloon catheter having a stainless steel hypotube catheter shaft and a distal balloon. Certain sections of the device shown in the patent use a spiral ribbon of stainless steel secured to the outer sleeve by a suitable adhesive to act as a transition section from a section of very high stiffness to a section of comparatively low stiffness.

Japanese Kokai 05-220,225, owned by the Terumo Corporation, describes a catheter in which the torsional rigidity of the main body is varied by incorporating onto an inner tubular section 33, a wire layer which is tightly knitted at the proximal section of the catheter and more loosely knitted at a midsection.

Single-Layer, Reinforced Catheters

There are a variety of catheters which, unlike the devices discussed above, utilize but a single layer of reinforcing material.

For instance, U.S. Pat. No. 243,396 to Pfarre, patented in June of 1881, shows the use of a surgical tube having a wire helix situated within the tube wall. The wire helix is said to be vulcanized into the cover of the device.

U.S. Pat. No. 2,211,975, to Hendrickson, shows a similar device also comprising a stainless steel wire 15 embedded in the inner wall of a rubber catheter.

U.S. Pat. No. 3,757,768, to de Toledo, shows a "unitary, combined spring guide-catheter that includes an inner wall portion formed as a continuous helical spring with the helices in contact with each other and an outer wall portion formed from an inert plastic material enclosing the spring in such a manner as to become firmly bonded to the spring while having its outer surface smooth". There is no suggestion to separate the windings of the coil in any fashion.

U.S. Pat. No. 4,430,083 describes a catheter used for percutaneous administration of a thrombolytic agent directly

to a clot in a coronary artery. The device itself is an elongated, flexible tube supported by helically wound wire having a specific cross-sectional shape. The wire is wound into a series of tight, contiguous coils to allow heat shrinking of tubing onto the outside of the wire of the shape of the outer surface of the wire as wound into the helix provides the heat-shrunk tubing with footing for a tight fit.

U.S. Pat. No. 4,567,024, to Coneys, shows a catheter which employs a set of helical strips within the wall of the catheter. However, the helical strips are of a radiopaque material, e.g., fluorinated ethylene-propylene. It is not clear that the blended radiopaque material necessarily provides any physical benefit other than the ability to allow the catheter shaft to be seen when viewed with a fluoroscope.

U.S. Pat. No. 4,737,153, to Shimamura et al., describes a device which is characterized as a "reinforced therapeutic tube" and which uses a spiral reinforcing material embedded within the wall of the device.

U.S. Pat. No. 5,069,674, to Fearnot et al. (and its parent, U.S. Pat. No. 4,985,022), shows a small diameter epidural catheter having a distal tip made up of a stainless steel wire which is helically wound and placed within a tubular sheath or tube. There is no suggestion within the patent that the interior coil be made to adhere to the outer tubular sheath.

Similarly, U.S. Pat. No. 5,178,158, to be Toledo, shows what is characterized as a "convertible wire for use as a guidewire or catheter". The patent describes a structure which comprises an interior wire or spring section shown, in the drawings, to be of generally rectangular cross-section. Outer layers of the device include a polyamide sheath placed adjacent to the helical coil at the proximal end of the catheter (see column 4, lines 64 and following). The device also comprises an outer sheath 40 of Teflon that extends from the proximal end 12 to the distal end 14 of the device. The overlying sheath 40 may extend or overhang at the proximal or the distal end of the catheter. The distal tip portion 13 is said to be "flexible, soft, and floppy". There is no suggestion of utilizing an adhesive to bond the interior wire to the exterior tubing. The PCT Published Application corresponding to this patent is WO 92/07507.

U.S. Pat. No. 5,184,627 shows a guidewire suitable for infusion of medicaments to various sites along the guidewire. The guidewire is made up of a helically wound coil having a polyamide sheath enclosing its proximal portion and a Teflon sheath tightly covering the entire wire coil. The coil is closed at its distal end. There is no suggestion that the wire forming the helical core be adhesively attached to its outer coverings.

U.S. Pat. No. 5,313,967, to Lieber et al., shows a medical device, a portion of which is a helical coil which apparently may include an outer plastic sheath in some variations. Apparently, a secondary helix of a somewhat similar design (in that it is formed by rotating a flat wire or the like along its longitudinal axis to form a screw-like configuration) is included within the helical coil to provide axial pushability and torque transmission.

U.S. Pat. No. 5,405,338, to Kranys, describes a helically wound catheter incorporating a shaft component having a helically wound coil with a skin or webbing supported by the coil. The skin or webbing is said to contribute "negligibly to the resistance of the catheter to axially directed compressive forces . . ." The catheter may include an inner, taut skin component.

The PCT application, WO 93/15785, to Sutton et al., describes kink-resistant tubing made up of a thin layer of an encapsulating material and a reinforcing coil. As is shown in

the drawings, the supporting material is embedded within the wall of the tubing in each instance.

The PCT application bearing the number WO 93/05842, to Shin et al., shows a ribbon-wrapped catheter. The device is shown as a section of a dilatation catheter. The inner section 34 is a helically wound coil and is preferably a flat wire. See, page 6, lines 25 and following. The coil is then wrapped with a heat-shrunk jacket 34 formed of low-density polyethylene. A lubricious material such as a silicone coating may then be placed on the inner surface of the spring coil to "enhance handling of the guidewire". It is also said, on page 6 of the document, that the

"entire spring coil, before it is wound or jacketed, may be coated with other materials such as Teflon to enhance lubricity or provide other advantages. In some embodiments, the spring coil has been plated with gold."

Endoscope Structures

Various endoscopic structures, used primarily in sizes which are larger than endovascular catheters utilize structures including stiffener materials.

U.S. Pat. No. 4,676,229, to Krasnicki et al., describes an endoscopic structure 30 having an ultrathin walled tubular substrate 31 formed of a lubricious material such as TEFLON. The structure contains a filament supported substrate. The filament is coated with and embedded into a filler material, typically an elastomeric material. A highly lubricious outer coating 35, all as shown in FIG. 2, forms the outer layer of the device. FIG. 3 in Krasnicki et al., describes another variation of the endoscopic device in which a different selection of polymer tubing is utilized but the placement of the filamentary support remains varied in an intermediate material of an elastomer. In some variations of the device, the filament is strongly bonded to the inner tubular substrate using an adhesive 37 "such as an epoxy cement having sufficient bond strength to hold the filament to the substrate as it is deformed into a tight radius." See, column 3, lines 50 and following.

U.S. Pat. No. 4,899,787, to Ouchi et al. (and its foreign relative, German Offenlegungsschrift DE-3242449) describes a flexible tube for use in an endoscope having a flexible, basic tubular core structure made up of three parts. The three parts are an outer meshwork tube, an intermediate thermoplastic resin tube bonded to the outer meshwork tube, and an inner ribbon made of a stainless steel or the like which is adherent to the two polymeric and meshwork tubes such that the resin tube maintains an adherent compressive pressure in the finished flexible tube. The patent also suggests the production of an endoscope tube having "flexibility which varies in step-wise manner from one end of the tube to the other . . . [and is produced] by integrally bonding two or more thermoplastic resin tube sections formed of respective resin materials having different hardnesses to the outer surface of the tubular core structure . . .". See, column 2, lines 48 and following.

U.S. Pat. No. 5,180,376 describes an introducer sheath utilizing a thin, flat wire metal coil surrounded only on its exterior surface with a plastic tube of coating. The flat wire coil is placed there to lower the "resistance of the sheath to buckling while minimizing the wall thickness of the sheath." A variation using two counter-wound metal ribbons is also described. No suggestion of the use of an adhesive is made in the patent.

European Patent Application 0,098,100 describes a flexible tube for an endoscope which uses a helically wound

metallic strip having a braided covering contiguous to the outer surface of the coil and having still further out a polymeric coating 9. Interior to the coil is a pair of slender flexible sheaths which are secured to a "front-end piece 10" by soldering.

Japanese Kokai 2-283,346, describes a flexible endoscope tube. The tubular outer shell is made up of two layers of a high molecular weight laminated material. The tube also has an inner layer of an elastic material and interior to it all is a metallic ribbon providing stiffening.

Japanese Kokai 03-023830, also shows the skin for flexible tube used in an endoscope which is made up of a braid 3 prepared by knitting a fine wire of a metal with a flexible portion 2 which is prepared by spirally winding an elastic belt sheet-like material and a skin 4 with which the whole outer surface of the device is covered. The document appears to emphasize the use of a particular polyester elastomer.

Japanese Kokai 5-56,910, appears to show a multi-layered endoscope tube made up of layers of the spiral wound metallic ribbon covered by a polymeric sheath.

French Patent Document 2,613,231, describes a medical probe used with an endoscope or for some other device used to stimulate the heart. The device appears to be a helix having a spacing between 0 and 0.25 mm (See page 4, line 20) preferably rectangular in cross section (See Page 4, Line 1) and of a multi-phase alloy such as M35N, SYNTACOBEN, or ELGELOY (See page 4).

German Offenlegungsschrift DE-3642107 describes an endoscope tube, formed of a spiral tube, a braid formed of fibers interwoven into a net (which braid is fitted on the outer peripheral surface of the spiral tube), and a sheath covering the outer peripheral surface of the braid.

None of the noted devices have the structure required by the claims recited herein.

Other Anti-kinking Configurations

U.S. Pat. No. 5,222,949, to Kaldany, describes a tube in which a number of circumferential bands are placed at regular intervals along a catheter shaft. The bands may be integrated into the wall of the catheter. A variety of methods for producing the bands in the tubular wall are discussed. These methods include periodically irradiating the wall to produce bands of a higher integral of cross-linking.

European Patent Application No. 0,421,650-A1 describes a method for producing a catheter from a roll of polymer film while incorporating other materials such as tinfoil elements or the like.

None of the documents cited above provides a structure required by the disclosure and claims recited below, particularly when the flexibility and ability to resist kinks is factored into the physical description of the devices.

SUMMARY OF THE INVENTION.

This invention is a catheter section made up of an inner liner and an outer covering and having a superelastic alloy braid located between the liner and the covering. The inner liner may be of a polymeric composition or of a helical coil desirably metallic. The inner liner and the outer covering, should they be adjacent the braid and both polymeric, preferably are selected from polymers which are melt-compatible or melt-miscible with each other. In this way, adjacent polymeric layers hold fast to the braid located between them. The inner liner may also be a helical coil of ribbon or wire.

The superelastic alloy braid is, in its most basic form, a braid comprising a number of small superelastic alloy ribbons wound and treated in such a way that the resulting braid is dimensionally stable and the ribbons do not twist. The more basic forms of braids used in this invention include those which are made up of an even number of equally sized ribbons. Half of the ribbons are woven in a clockwise direction (as viewed along the axis of the braid) and the remaining half of the ribbons are woven in a counterclockwise direction. The various ribbons may, of course, be of differing size but the sum of the ribbons used in a particular direction should equal those wound in the other direction. Any imbalance will typically cause a helical curl in the resulting catheter. The superelastic alloy of choice is one known generically as Nitinol. Nitinol is an alloy of nickel and titanium which is blended and heat treated in a specific way to produce an alloy having exceptional resistance to plastic deformation upon physical strain. In addition to nickel and titanium, preferred compositions of the alloy contain a modest amount, up to about 5%, of an iron group alloy, particularly chromium or iron. The catheter section may additionally have other various layers of polymeric covering or metallic tubing members desirably of braid or helical coils. Hydrophilic coatings both on the interior and exterior are additionally contemplated.

The kink resistance of the catheter section is due to the presence of the braid. In addition to exceptional kink resistance, the catheter section may be made in such a way that the wall is extraordinarily thin, particularly when compared to walls of catheters having equal strength but made solely of polymeric materials. The catheter section additionally is very resilient in that, unlike virtually any other commercial catheter, should the catheter section be kinked, the kink is self-healing. This resiliency means that the catheter need not be withdrawn from a patient's vasculature simply because the catheter has inadvertently kinked. Simple movement of the catheter will cure the kink. Kinking minimization is a matter of concern with many catheters in the marketplace today.

This invention additionally includes braids having more than one pitch in a single section. The stiffness of the catheter section may be varied continuously by continuously varying the pitch or in a stepwise fashion by stepwise varying the pitch. The pitch may be varied upon production of the braid or by changing the diameter of the braid after production.

The catheter section of this invention may be used as a catheter assembly by itself—obviously in conjunction with such necessary and ancillary components as a Luerlock and some manner of providing radiopacity to the catheter. The catheter section of this invention may be used in nose-to-tail configuration with other catheter sections of similar configuration or with catheter sections made in some other fashion.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows, in side view, a typical three-section catheter made using the concepts of this invention.

FIGS. 2, 3, 4, and 5 show, in magnification, a partial cross-section of the inner portion of a catheter section using this invention.

FIGS. 6, 7, 8, 9, and 10 show, in magnified cross-section, various catheters having sections of differing stiffness.

FIGS. 11A and 11B show details of methods for determining "critical bend diameter" for a catheter section.

DESCRIPTION OF THE INVENTION

This invention is a kink-resistant catheter section containing at least an inner liner and a flexible outer member having

a superelastic alloy, a ribbon braid between the inner and outer members. The invention is also a catheter made up using at least one catheter section made according to the invention. The catheter section is configured so that it desirably has a critical bend diameter of no more than about 3 mm., preferably no more than 2 mm., and most preferably no more than 1 mm. Desirably, the catheter section self-recovers at least 95% of its original "straightness" after it has been subjected to kinking.

A typical multi-section catheter (100) which may incorporate the concepts of this invention is shown in FIG. 1. Such a catheter is described in more detail in U.S. Pat. No. 4,739,768, to Engelson, (the entirety of which is incorporated by reference) and is particularly suitable for neurological and peripheral vascular applications. Clearly, then, it is also suitable for less demanding service such as might be encountered in access and treatment of the heart. One difficulty which has arisen as higher demands for length have been placed on these catheters is that the diameter of the distal section necessarily becomes smaller and smaller. This is so since the longer catheters must reach ever more smaller vascular areas. This smaller diameter requires a concomitant thinning of the wall section. The thinner section walls may kink or ripple when actively pushed along the guidewire or when vaso-occlusive devices are pushed through the catheter's lumen. The typical configuration shown in FIG. 1 has a distal section (102) having significant flexibility, an intermediate section (104) which is typically less flexible, and a long proximal section (106) which in turn is least flexible. The distal section (102) is flexible and soft to allow deep penetration of the extraordinary convolutions of the neurological vasculature without trauma. Various known and often necessary accessories to the catheter assembly, e.g., one or more radiopaque bands (108) at the distal region to allow viewing of the position of the distal region under fluoroscopy and a luer assembly (110) for guidewire (112) and fluids access, are also shown in FIG. 1. The typical dimensions of this catheter are:

Overall length: 60–200 cm

Proximal Section (106): 60–150 cm

Intermediate Section (104): 20–50 cm

Distal Section (102): 2.5–30 cm

Obviously, these dimensions are not particularly critical to this invention and are selected as a function of the malady treated and its site within the body. Typical of the catheters made using this invention are those in the 2 French to 5 French range. The inner diameter of such catheters is then 10 mils to 42 mils.

Furthermore, a catheter made using this inventive concept need not be of three sections increasing stiffness as is shown in FIG. 1. The catheter may be of two discrete sections or may be of four or more discrete sections of differing flexibility. Through judicious choice of physical parameters for the catheter sections, the components may also have varying physical parameters (e.g., lubricity, flexibility, wall thickness, inner or outer layer member composition, etc.) within the sections. An additional benefit of the invention is that the use of the superelastic braid permits the walls of the catheter to be comparatively thinner with no diminution of performance, e.g., crush strength or flexibility, and provides an improvement in performance.

FIG. 2 shows a magnified partial cross-section of a catheter body or section (200) showing the most basic aspects of one variation of this invention. As shown there, the catheter body section has an outer covering member (202) and an inner liner member (204). Situated between

outer member (202) and inner member (204) is braid member (206). As shown in FIG. 2, both outer member (202) and inner member (204) are polymeric. They are desirably selected of materials which tack to each other upon heating. They may also be melt-miscible. In some instances, they may contain components which act in the manner of adhesives, but such is not necessary. Typically, for the simple variation shown in FIG. 2, the outer covering member (202) is of a material which is heat-shrinkable onto the inner member (204) and the braid (206). Preferred polymeric materials for the inner liner include polyethylene, polyvinyl chloride (PVC), ethyl vinyl acetate (EVA), polyethylene terephthalate (PET), and their mixtures and copolymers. Another useful class of polymers are thermoplastic elastomers, including those containing polyesters as components. Typical of this class is HYTREL. Additionally, an adhesive may be coated onto the inner liner tubing. Polyesters and polyimides, in particular, are useful as adhesives in this service.

An outer covering of polyethylene or of EVA is an excellent choice for the outer covering member. The polymer is typically extruded into a tubing of appropriate size and thickness and then crosslinked to raise the melt temperature of the resulting tubing. The tubing is then inflated and perhaps stretched to give the included polymer a specific molecular orientation. The tubing, so treated, may then be slipped over the combination of inner liner (204) and braid (206) and heat shrunk into place.

A variety of other polymers may be used, depending upon the use to which the catheter section is placed. For instance, if the section (200) is used as a proximal section, the outer tubing may be a polyimide, polyamides (such as the Nylons), high density polyethylene (HDPE), polypropylene, polyvinylchloride, various fluorocarbon polymers (for instance: PTFE, FEP, vinylidene fluoride, their mixtures, alloys, copolymers, block copolymers, etc.), polysulfones, or the like. Blends, alloys, mixtures, copolymers and block copolymers of these materials are also suitable if desired.

If a more flexible section is required, the outer tubing member (202) may also be of a member selected from a more flexible material such as polyurethanes, low density polyethylene (LDPE), polyvinylchloride, THV, etc. and other polymers of suitable softness or a modulus of elasticity.

FIG. 2 shows the results of either a heat-shrinking the outer tubing member (202) onto the assembly of inner liner tube (204) and braid (206). Contact regions between the outer covering member (202) and inner liner member (204) are shown in the interstices between the open weave of the braid (206). Although the open area between turns of the braid is not absolutely necessary as a means of allowing contact between the inner liner (204) and the outer covering (202), such is quite desirable. Furthermore, when the outer covering member (202) is placed on the outer surface of the catheter section (200) by dipping the inner assembly of braid (206) and inner member (204) into a molten or latex liquid, the contact is inevitable.

The wall thickness of the outer tubing member (202) may be as thin as 0.5 mils. and as thick as 10 mils., depending upon catheter usage, section of the catheter chosen, polymer choice, and style of catheter.

Typically, a wall thickness of the inner liner (204) will be between 0.5 and 3.0 mils. These dimensions are obviously only ranges and each catheter variation must be carefully designed for the specific purpose to which it is placed.

Each of the polymers noted herein may be used in conjunction with radiopaque filler materials such as barium

sulfate, bismuth trioxide, bismuth carbonate, powdered tungsten, powdered tantalum, or the like so that the location of various portions of the catheter sections may be radiographically visualized within the human body.

As will be discussed below, it is within the scope of this invention to have multiple polymeric layers exterior of the braid (206) as well as multiple polymeric liner members interior to braid (206). Furthermore, it is within the scope of the invention to include multiple braids and/or flat ribbon coils between or amongst the various polymeric layers.

It is also within the scope of this invention to coat at least one of the exterior surface of outer member (202) and the inner surface of inner liner (204) with a lubricious layer, which either is chemically bonded to the layer or is physically coated on the relevant surface. A description of suitable procedures for producing such lubricious coatings is found at U.S. patent application Ser. Nos. 08/060,401 ("LUBRICIOUS CATHETERS"), filed May 12, 1993; 08/235,840 ("METHOD FOR PRODUCING LUBRICIOUS CATHETERS"), filed Apr. 29, 1995; and 08/272,209 ("LUBRICIOUS FLOW DIRECTED CATHETER"), filed Jul. 8, 1994, the entirety of which are incorporated by notice. The metallic braid (206) shown in FIG. 2 is made up of a number of metallic ribbons. A majority of the metallic ribbons in braid (206) are of a member of a class of alloys known as superelastic alloys.

Preferred super-elastic alloys include the class of titanium/nickel materials known as nitinol—alloys discovered by the U.S. Navy Ordnance Laboratory. These materials are discussed at length in U.S. Pat. Nos. 3,174,851 to Buehler et al., 3,351,463 to Rozner et al., and 3,753,700 to Harrison et al. Commercial alloys containing up to about 5% of one or more other members of the iron group, e.g., Fe, Cr, Co, are considered to be encompassed within the class of superelastic Ni/Ti alloys suitable for this service.

When using a superelastic alloy, an additional step may be desirable to preserve the shape of the stiffening braid. For instance, with a Cr-containing Ni/Ti superelastic alloy which has been rolled into a 1×4 mil ribbon and formed into a 16-member braid, some heat treatment is desirable. The braid is placed onto a mandrel, usually metallic, of an appropriate size. The braid is then heated to a temperature of 650°–750° F. for a few minutes, possibly (but not necessarily) annealing the constituent ribbon. After heat treatment, the braid retains its shape and the alloy retains its superelastic properties.

Metallic ribbons (202) that are suitable for use in this invention are desirably between 0.25 mil and 3.5 mil in thickness and 2.5 mil and 12.0 mil in width. By the term "ribbon", I intend to include elongated shapes, the cross-section of which are not square or round and may typically be rectangular, oval or semi-oval. They should have an aspect ratio of at least 0.5 (thickness/width). In any event, for superelastic alloys, particularly nitinol, the thickness and width may be somewhat finer, e.g., down to 0.30 mil and 1.0 mil, respectively. Currently available ribbons include sizes of 1 mil×3 mil, 1 mil×4 mil, 2 mil×6 mil, and 2 mil×8 mil.

The ribbons making up the braid (206) shown in FIG. 2 may also contain a minor amount of non-superelastic materials. Although metallic ribbons are preferred as the ancillary materials because of their strength-to-weight ratios, fibrous materials (both synthetic and natural) may also be used. Preferred, because of cost, strength, and ready availability are stainless steels (SS308, SS304, SS318, etc.) and tungsten alloys. In certain applications, particularly smaller diameter catheter sections, more malleable metals and alloys, e.g., gold, platinum, palladium, rhodium, etc. may be used. A

platinum alloy with a few percent of tungsten is preferred partially because of its radiopacity.

Suitable non-metallic ribbons include high performance materials such as those made of polyaramids (e.g., KEVLAR) and carbon fibers.

The braids utilized in this invention may be made using commercially available tubular braiders. Whenever I use the term "braid" herein, I mean tubular constructions in which the ribbons making up the construction are woven in an in-and-out fashion as they cross to form a tubular member defining a single lumen. The braids may be made up of a suitable number of ribbons, typically six or more. Ease of production on a commercial braider typically results in braids having eight or sixteen ribbons.

The braid shown in FIG. 2 has a nominal pitch angle of 45°. Clearly the invention is not so limited. Other braid angles from 20° to 60° are also suitable. An important variation of this invention is the ability to vary the pitch angle of the braid either at the time the braid is woven or at the time the braid is included in the catheter section or sections.

Finally, the inner liner may be of a helically wound coil of wire or ribbon. The composition of the coil may be of any of the materials listed above for use in constructing the braid. The preferred materials for this metallic version of catheter section inner liner are the superelastic alloys (especially the noted group of Nitinols), stainless steels, and the radio-opaque metals and alloys (for instance, platinum alloys, especially platinum alloys with tungsten). These metallic liners may be made in the manner specified in detail in U.S. application Ser. No. 08/266,540 "Kink-Free Spiral Wound Catheter", filed Jun. 27, 1994 and in U.S. application Ser. No. 08/338,018 "High Performance Spiral Wound Catheter", filed Nov. 10, 1994, the entirety of which are incorporated by reference..

FIG. 3 shows a variation of the invention in which the braid (206) is used in a catheter section (208) having two portions of different diameter. The larger diameter portion (210) utilizes the braid with a nominal braid angle of 45 degrees and a smaller diameter portion (212) in which the same braid has a braid angle of 30 degrees. This diminution in catheter diameter may be accomplished in a number of different ways. For instance, inner liner (214) may be sized with two different diameters in the respected different portions (210 and 212) of the catheter section. The braid (206) may then be stretched axially as it is placed upon that liner. When the outer covering (216) is placed on the braid (206), the braid (206) will retain its multi-diameter configuration. This variation has the benefit of being quite simple in construction and yet provides a variety of different flexibilities to the catheter section without a significant change in the materials of construction.

FIG. 4 shows another variation of the inventive catheter section (218) in which the braid is constructed of ribbons of different width. In this instance, the section (218) includes a braid having a wide ribbon (220) and a narrower ribbon (222). As noted above, it is desirable to balance the size and types of ribbons woven in each direction. As also noted above, these various ribbons should be, in the main, superelastic alloy. However, they may be fibrous materials such as Kevlar or materials of other metals or alloys such as stainless steel. However, to accomplish the benefits of the invention, the major portion of the ribbons making up a braid should be superelastic alloy.

The variations shown above have each shown a single-ribbon wind. Single-ribbon winds permit the braid to contain the maximum amount of open area between ribbons in the

braid. However, the catheter section need not be made with a single wind. FIG. 5 shows a variation of the inventive catheter section (226) in which the braid (228) was woven using a double-ribbon wind. In this variation, a pair of ribbons is placed side by side and treated as the single ribbon was in the variations described in FIGS. 2–4 above. This variation produces a braid which is denser than the single-ribbon wind. Typically, the regions between adjacent winds are smaller. The invention described herein is intended to encompass multiple-wind braids. However, some of the benefits of the invention are diminished as the density of the ribbons in the catheter section is increased. That is to say that the stiffness of the catheter section substantially increases as the number of ribbons used in a multiple-ribbon weave is increased. The catheter sections shown in FIGS. 2, 3, 4, and 5 may be combined in a variety of manners to produce a composite catheter assembly. As I mentioned above, the typical vascular catheter is made up of a number of sections, typically each more flexible than the section more proximal. FIGS. 6–10 show various ways to utilize the catheter sections of this invention in producing a catheter with sections of differing stiffness. In FIG. 6, catheter assembly (224) uses a single length of braid (226) extending from the proximal end of the catheter assembly (224) throughout the proximal section of the catheter (228) and throughout the midsection of the catheter (230). The distal section of the catheter (232) does not have braid (226) within. The difference in flexibility between proximal section (228) and midsection (230) lies in the fact that the inner liner members (234) in midsection (230) and inner liner (236) in proximal catheter section (228) are of differing moduli of elasticity. In this variation, the outer layer is a single piece of shrink-wrap tubing, e.g., polyethylene, which extends both other the composite proximal end (228) and midsections (226). It extends to form the distal section as well. Such a catheter design would be one desirable in neurological use, that is, to reach into sites within the brain.

FIG. 7 shows another variation of a catheter assembly made using multiple layers of braided sections made according to the invention. This catheter assembly (240) uses a proximal section (242) made up of a number of layers but including an inner braid (244) and an outer braid (246). The inner braid (244) also extends down into and extends through the length of midsection (248). In this variation, the inner liner member (250) coextends, is coaxial with, and is internal to the inner braid (244). A middle layer of a polymeric tubing (254) extends from the proximal end of the catheter to the distal end of the catheter and forms the distal portion (252) of that catheter assembly. A further outer covering (256) covers braid (246).

Designs such as is shown in FIG. 7 is one of exceptional stiffness in the proximal section (242). Although not critical for most neurological applications, such a catheter design has exceptional torque transmission. Such a catheter design may be desirable where a catheter is used for coronary or peripheral access.

Another catheter design desirable for peripheral or coronary access is shown in FIG. 8. In this variation, catheter assembly (260) includes a tubing liner (262) which extends throughout the complete catheter assembly (260) from proximal section (264) through midsection (266) to distal section (268). More importantly, the braid (270) also coextends the length of inner liner (262). Differences in flexibility for the respective sections are provided by the use of polymeric tubing members (272) for the proximal section (264) and midsection tubing member (274) for the catheter assembly midsection (266). The absence of additional poly-

meric members other than the outer polymeric covering (276) renders distal section (268) the most flexible.

FIGS. 9 and 10 show cross-sectional, partial cutaways of catheter assemblies utilizing braided catheter sections joined to more distal catheter sections made in other ways. In the variation shown in FIG. 9, a coil (282) is placed in the more distal portion of the catheter assembly. It butts the single-layer of braid (284) axially. Similarly, in claim 10, a ribbon (286) is used in the distal portion (288) of catheter assembly (290). The braid is used only in the remaining portion of the catheter assembly (290).

Again, it should be noted that although the exemplified catheter assemblies in FIGS. 6, 7, 8, 9, and 10 utilize only two or three sections, this invention is not so limited. The number of sections is selected by the designer when conceptualizing a specific use for a chosen device. Often, the optimum number of sections ends up being three simply because of the physiology of the human body, however, three or more may be involved in this invention. The sections additionally need not be of constant stiffness. They may also vary in stiffness—typically as the distal end of a section is approached, the section becomes more flexible.

The test I utilize for critical bend diameter determination uses a test shown schematically in FIGS. 11A and 11B.

In general, as shown in FIG. 11A, a catheter section (300) is placed between two plates (desirably of plastic or glass or the like for visibility) and often with an optional peg (302) to hold the catheter section loop in place. The ends of the catheter are then pulled until a kink appears in the body of the catheter. Alternatively, the ratio of the outer diameters (major diameter:minor diameter) as measured at apex (304) reaches a value of 1.5. FIG. 11B shows the cross section of the catheter sector at (304) and further shows the manner in which the major diameter and the minor diameter are measured. These two methods provide comparable results although the latter method is more repeatable.

Many times herein, I refer to the “region” section of the catheter. Where the context permits, by “region” I mean within 15% of the point specified. For instance, “the distal region of the distal section” would refer to the most distal 15% in length of the distal section.

EXAMPLE 1

I constructed a catheter having three regions of differing flexibility. The most distal region was the most flexible. The catheter was completely lined from proximal end to distal end. The braid extended from proximal end to distal end. The braid was woven from eight ribbons of a commercial Nitinol alloy containing about 2% Cr (sold by Shape Memory Applications Co. of Santa Clara, Calif.). The alloy had a thermal transition temperature (between austenitic and martensitic phases) of -10° C. The braid was placed on a 0.024" diameter stainless steel mandrel and heat-treated at 650° – 700° F. for 15–30 minutes to permit the braid to maintain its shape. A liner of a PTFE/FEP blend tubing was placed within the braid. The proximal section was covered with a tubing of Schorr 72D polyurethane; the midsection was covered with a tubing of Schorr 60D polyurethane; the distal section was covered with a tubing of Schorr 85A polyurethane. The polyurethane tubing members were of a commercial resin sold under the CARBOTHANE trademark. The resulting had a 0.038" O.D. The distal section had a critical bending diameter of 3 mm.

EXAMPLE 2

I constructed a second catheter also having three regions of differing flexibility of the same polymers as the catheter

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in Example 1. The most distal region was the most flexible. In this instance, the catheter was completely lined from proximal end to distal end with a nitinol ribbon coil. The ribbon was a 1 mil by 6 mil nitinol ribbon which was tightly wound, i.e., with substantially no space between adjacent turns. The braid extended from proximal end to distal end axially between the ribbon coil and the polymeric outer covering. The braid was again woven from eight ribbons of the alloy mentioned in Example 1. The outer covering was of the same composition as the Example 1 catheter. The resulting catheter had a 0.038" O.D. The distal section appeared to have a critical bending diameter of 2.5 mm.

This invention has been described and specific examples of the invention have portrayed. The use of those specifics is not intended to limit the invention in any way. Additionally, to the extent that there are variations of the invention which are within the spirit of the disclosure and yet are equivalent to the inventions found in the claims, it is our intent that those claims cover those variations as well.

I claim as my invention:

1. A catheter section comprising:
an elongate tubular member having a proximal end and a distal end and a passageway defining an inner lumen extending between those ends, comprising
 - a.) a tubular braid member woven of a plurality of ribbons, at least a majority of which ribbons comprise a superelastic alloy, and having inner and outer surfaces, which braid member has been heat-treated after weaving of said braid member to retain the tubular braid shape,
 - b.) at least one inner lining member interior to said braid member, and
 - c.) at least one outer covering member exterior to said braid member.
2. The catheter section of claim 1 wherein the superelastic alloy comprises a nickel-titanium alloy.
3. The catheter section of claim 1 wherein at least one of the inner lining member and the outer covering member are polymers.
4. The catheter section of claim 3 wherein the polymers are selected from members selected from the group consisting of polyimides, polyamides, polyesters, polyethylene, polypropylene, polyvinylchloride, polyfluorocarbons, polyurethanes, polysulfones, and their mixtures, alloys, blends, copolymers, and block copolymers.
5. The catheter section of claim 1 wherein the superelastic alloy is nitinol.
6. The catheter section of claim 1 wherein a minority of the braid member ribbons are stainless steel.
7. The catheter section of claim 1 wherein a minority of the braid member ribbons comprise platinum.
8. The catheter section of claim 1 wherein the inner liner and outer covering members are radiation sterilizable without substantial degradation of physical attributes.
9. The catheter section of claim 1 wherein the braid member has a braid pitch and that braid pitch is constant along the axis of the braid member.
10. The catheter section of claim 1 wherein the braid member has a braid pitch and that braid pitch is not constant along the axis of the braid member.
11. The catheter section of claim 1 where the braid member ribbons have a thickness between 0.5 mil and 3.5 mil and a width between 2.5 and 12.0 mil.
12. The catheter of claim 1 wherein at least one of the inner liner member and the outer covering member is radiopaque.
13. The catheter section of claim 1 where the inner liner comprises a coil.

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14. The catheter section of claim 1 where the inner liner comprises a ribbon coil of a material selected from superelastic alloys, stainless steels, and radiopaque alloys.

15. The catheter section of claim 14 where the inner liner comprises a ribbon coil of a nickel-titanium alloy.

16. The catheter section of claim 14 where the inner liner comprises a ribbon coil of a stainless steel.

17. The catheter section of claim 14 where the inner liner comprises a ribbon coil of a platinum-tungsten alloy.

18. The catheter section of claim 1 further comprising a removable, slidable guidewire placed interior to and in slidable relationship to said section.

19. The catheter section of claim 1 wherein the inner lining member comprises a polymer.

20. The catheter section of claim 19 wherein the inner lining member comprises a polyfluorocarbon polymer.

21. The catheter section of claim 19 wherein the outer covering member comprises a polymer.

22. The catheter section of claim 1 wherein the outer covering member comprises a polymer.

23. The catheter section of claim 22 wherein the outer covering member comprises a polyurethane polymer.

24. The catheter section of claim 23 wherein the outer covering member further comprises a polyethylene polymer.

25. A catheter section comprising:
an elongate tubular member having a proximal end and a distal end and a passageway defining an inner lumen extending between those ends,

said elongate tubular member having:

- a.) a relatively stiff proximal segment, and
- b.) a relatively flexible distal segment,

at least one of the proximal and distal segment comprising a catheter section having a proximal end and a distal end and a passageway defining an inner lumen extending between those ends, comprising

- i.) a tubular braid member woven of a plurality of ribbons, at least a majority of which ribbons comprise a superelastic alloy, and having inner and outer surfaces, which braid member has been heat-treated after weaving of said braid member to retain the tubular braid shape,
- ii.) at least one inner lining member interior to said braid member, and
- iii.) at least one outer covering member exterior to said braid member wherein the segment comprising the braid has a critical bend diameter of no more than 3 mm.

26. The catheter of claim 25 wherein the braid member has a braid pitch and that braid pitch is constant along the axis of the braid member.

27. The catheter of claim 25 wherein the braid member has a braid pitch and that braid pitch is not constant along the axis of the braid member.

28. The catheter of claim 19 where the braid member ribbons have a thickness between 0.5 mil and 3.5 mil and a width between 2.5 and 12.0 mil.

29. The catheter of claim 19 wherein at least one of the inner liner member and the outer covering member is radiopaque.

30. The catheter section of claim 19 where the inner liner comprises a coil.

31. The catheter section of claim 19 where the inner liner comprises a ribbon coil of a material selected from superelastic alloys, stainless steels, and radiopaque alloys.

32. The catheter section of claim 31 where the inner liner comprises a ribbon coil of a nickel-titanium alloy.

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- 33. The catheter section of claim 31 where the inner liner comprises a ribbon coil of a stainless steel.
- 34. The catheter section of claim 31 where the inner liner comprises a ribbon coil of a platinum-tungsten alloy.
- 35. The catheter of claims 31 further comprising a removable, slidable guidewire placed interior to and in slidable relationship to said catheter.
- 36. The catheter of claim 25 wherein the inner lining member comprises a polymer.
- 37. The catheter of claim 36 wherein the inner lining member comprises a polyfluorocarbon polymer.
- 38. The catheter of claim 25 wherein the outer covering member comprises a polymer.
- 39. The catheter of claim 38 wherein the outer covering member comprises a polymer.
- 40. The catheter of claim 39 wherein the outer covering member comprises a polyurethane polymer.
- 41. The catheter of claim 40 wherein the outer covering member further comprises a polyethylene polymer.

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- 42. The catheter of claim 25 wherein the super-elastic alloy comprises a nickel-titanium alloy.
- 43. The catheter of claim 25 wherein at least one of the inner lining member and the outer covering member are polymers.
- 44. The catheter of claim 43 wherein the polymers are selected from members selected from the group consisting of polyimides, polyamides, polyesters, polyethylene, polypropylene, polyvinylchloride, polyfluorocarbons, polyurethanes, polysulfones, and their mixtures, alloys, blends, copolymers, and block copolymers.
- 45. The catheter of claim 25 wherein the superelastic alloy is nitinol.
- 46. The catheter of claim 25 wherein a minority of the braid member ribbons are stainless steel.
- 47. The catheter of claim 25 wherein a minority of the braid member ribbons comprise platinum.

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